FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATORY ADVISORY PANEL REGARDING CANNABIDIOL OIL AND THC-A OIL

July 1, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 10:10 am
PRESIDING:	Ryan K. Logan, Chairman (arrived 10:35am) Cynthia Warriner (10:10am-10:35am)
MEMBERS PRESENT:	Cynthia Warriner, Board of Pharmacy Jody H. Allen, Board of Pharmacy Svinder Toor, MD, Board of Medicine/ child neurologist William L. Harp, MD, Board of Medicine, Executive Director Alexander Pytlarz, Virginia Pharmacists Association Ed McCann, former owner of cannabis facility Regina Whitsett, Substance Abuse Free Environment, Inc. (SAFE) Beth Collins, Americans for Safe Access Baylor Rice, community compounding pharmacist Jake Bergman, Surterra Holdings Julia Whiting, MD, concerned parent/physician Chuck Moss, concerned family member (arrived 10:35am) Paul Lyons, MD, child neurologist
MEMBERS ABSENT:	Senator David W. Marsden
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Deputy Executive Director David E. Brown, DHP Director Elaine J. Yeatts, Senior Policy Analyst Jim Rutkowski, Assistant Attorney General Beth O'Halloran, Individual Licensing Manager
APPROVAL OF AGENDA:	The agenda was approved as presented.
PUBLIC COMMENT:	Lauren Schmitt, pharmacist representing Virginia Society of Health-System Pharmacists, provided comment and a letter from VSHP with suggested topics for the panel to consider. VSHP would like the panel to consider how cannabidiol oil and THC-A oil will be handled in hospitals with regard to patients being permitted to bring their own, hospitals having the ability to develop their own policy regarding administration, and where the oils for the certified patients will be stored. Ms. Schmitt requested that the panel consider these questions and include guidance in Regulation for hospitals on how to handle these oils.

Lennice Werth, an advocate for drug law reform, shared a personal account about her life with a seizure disorder and how marijuana positively affected her disorder and improved her life. Ms. Werth also commented that New Jersey's law on medical marijuana is too stringent and that she is glad to see Board of Pharmacy representation on the panel.

Mary Lynn Mathre, registered nurse and certified addiction specialist, is the co-founder of Patients Out of Time which educates the public and health professionals about the medical use of cannabis. Ms. Mathre also provided comment that she feels New Jersey's law is too stringent and requests that the panel consider ease of access for patients that require these oils.

AGENDA ITEMS:

- Presentation – summary of SB701 and Charge of Regulatory Advisory Panel

Caroline Juran, Executive Director for the Board of Pharmacy, provided an overview of SB 701 that permitted pharmaceutical processors to manufacture and provide cannabidiol oil and THC-A oil. Ms. Juran also provided a summary of the regulation 18VAC110-11-70 which affords the agency an allowance to appoint a regulatory advisory panel to provide professional or technical assistance and expertise to specific regulatory issues or actions.

- Presentation – general overview of the cannabis plant, methods for extracting cannabidiol oil and THC-A oil, treating intractable epilepsy with cannabidiol oil and THC-A oil

Dr. Paul Lyons provided a slideshow presentation of the medical literature regarding the use of medical marijuana in epilepsy patients. Several key points from the presentation are that there are 1% of the population with epilepsy and 1/3 of this population do not respond to currently approved drug therapy available. This translates to approximately 27,000 Virginians. Synthetic cannabidiol (dronabinol) was trialed and found not active enough to control seizure activity. The death rate in the U.S. due to epilepsy is 50,000 per year which would be 1,350 Virginians.

- Discussion questions

For the remainder of the meeting, Mr. Logan led a group discussion by soliciting feedback from the panel members in response to the discussion questions provided in the agenda packet and summarized below.

1. What standards in cultivating marijuana should be taken into consideration and/or regulated to ensure consistency in quality, potency, and mitigation of diversion?

Ms. Whitsett commented that pesticides should not be used at all in the production. Mr. Bergman agreed that pesticides should be prohibited or that at least fertilizers and pesticides used should require similar USDA standards for these products. Mr. McCann commented that regulations should not address how the processor does the manufacturing of the product. Mr. Bergman stated that the canopy size is generally based on the number of patients they are servicing. Mr. Bergman indicated a typical dose of oil is 200-500mg/patient/day and that 5-15gm of oil can be extracted from one plant. He estimates the facility would need approximately 1 plant per patient per month. Mr. Moss stated that there should be specific guidelines for cultivating the plant. Other comments

included: extraction process for the two oils is different and therefore, may need different number of plants depending on which oil is being produced; suggestion for gloves to be worn; reference to US organic standards; need a buffer amount of plants in case crop fails; standardization throughout the processors should be focused on potency expectation of 90-95%; need consistency in lab testing; suggestion to look at accreditation standards; need to track what works best; patients are interested in the ratio of ingredients in the oil and the ratios can be very patient-specific.

Action Item: **Mr. Bergman to provide information regarding basic requirements for temperature and humidity.**

2. What other physical standards must the pharmaceutical processor meet, e.g., room size, separate rooms, or space for various functions, etc.?

Ms. Whitsett stated there should be separate rooms for vegetation, cloning, flowering, drying, cultivating, clipping and quarantine. There should be a requirement for weights and scales and also proper ventilation in the rooms due to the strong odor of the additives used. Also a requirement that this facility be an indoor greenhouse. Other comments included: recommendation for indoor greenhouse without artificial light, but this may have impact on utilization of water; artificial lighting increases usage of power; need a controlled environment; not feasible to have walls in place for the vegetation to flowering stages; suggestion for seed to sale software requiring measurements in every step throughout the process.

3. What security requirements are appropriate to mitigate diversion, e.g., motion sensors throughout, video surveillance with 24 hour tape, etc.?

The discussion centered on that there should be possible requirements for security guards, cameras on all exterior and interior areas, and the area entirely fenced. Some members agreed that depending on the location of the facility, fencing the area may not be feasible. The panel agreed that, at minimum, there should be the same requirement for these facilities as there are for pharmacies and other facilities which are motion sensors throughout facility with back up monitoring.

4. What location restrictions should apply to pharmaceutical processors?

Ms. Whitsett commented that possibly should limit how close the facilities are to schools or recreational centers similar to ABC stores. Ms. Whitsett also commented that not placing these facilities in low income areas due to increased diversion should be discussed. Mr. Moss commented that since the amount grown would not be large we should not compare these facilities to that in Colorado or Washington DC which have facilities for recreational use. Ms. Collins stated that the facilities should be in proximity to the patients due to the fact that the patients must appear in person to pick up the medication. Dr. Whiting disagrees that the location should be limited and Mr. McCann agreed with Dr. Whiting.

Action Item: **Counsel to research whether SB701 would allow for a pharmaceutical processor to deliver dispensed oil to a patient's residence or if the registered patient/parent/legal guardian must pick up the oil at the site of the pharmaceutical processor.**

5. What is the maximum number of plants that a pharmaceutical processor should be allowed to possess at any given time?	One plant per person was discussed based on typical dose administered and typical amount of oil from each plant, however, difficult to define a maximum number of plants to be possessed. Will depend on cultivation techniques. Does a single tissue cell culture constitute a plant? Do cloning techniques impact the number of plants possessed? Need a buffer number of plants in case crop fails. The amount of cannabinoid is more associated with the canopy size, not the number of plants which will be at varying growing stages. DEA model references allowable number of mg of cannabinoid per facility.
Action Item:	**Mr. Bergman may be able to provide additional information on this subject to facilitate discussion.**
6. What minimum equipment and resources are necessary?	It was agreed that scales and weights are necessary equipment and ability to track inventory.
7. What recordkeeping should be required for the cultivation?	Mr. Bergman stated that there is seed to sale tracking software that the Board may want to require that a processor use which tracks all phases of growth, quality, and disposal. Examples include Priva, Agrisoft, and Biotrack THC. Suggested that some form of certificate of analysis be provided.
8. How and at what frequency is an inventory recordkeeping best performed to prevent or identify theft or loss of product?	It was agreed by the panel that the recordkeeping should be real-time, ongoing, and possibly through a tracking software.
9. What are the recommended methods for disposing of plant remains?	Mr. McCann suggested on site composting for disposing of the plant remains. Ms. Whitsett referenced concerns in Colorado for using dumpsters for disposal and that in Washington they mix the plant with a product prior to disposal.
10. Are there certain strains known to be better for producing cannabidiol oil or THC-A oil for the treatment of intractable epilepsy?	Dr. Lyons and Dr. Toor agreed that this depends on the patient and there needs to be flexibility in choice of strain. Suggested that a list of cultivars and ratios of ingredients be maintained in facility recordkeeping and shared with patients. Should test for ratios and terpenes. No one gold standard to identify preferred strain for patient.
11. How is cannabidiol oil and THC-A oil produced? What part of the plant is used? Comparison of the methods pros and cons? Should certain methods be permitted and others	Recommended that butane not be allowed in the extraction method and that carbon dioxide should be acceptable. Facility must use appropriate safety measures.

not due to a concern with safety or quality?	
12. To what standards should the production of oils be held, e.g. USP standards for non-sterile compounding or FDA good manufacturing practices for dietary supplements?	Mr. Rice commented that USP would be a better standard to rely on for this production as this is a drug and pharmacists are familiar with USP guidelines. Mr. Bergman agreed. Reference also made to the American Herbal Products Association. Dr. Toor stated that patients with Dravet Syndrome often start therapy at 2-3 weeks of age, therefore, need stringent requirements since not much room for error.
Action Item:	**Ms. Juran will research what standards are being required in other states.**
13. How is cannabidiol oil and THC-A administered? Any paraphernalia involved?	Normally this is administered orally or sublingually via oral syringe, however, it is possible to inhale via vaping or via nebulizer. Some may prefer capsules.
14. Are there public locations where it would be inappropriate for the oils to be administered?	There was some discussion that school nurses be allowed to administer to students and for hospital employees to administer to patients. This discussion will need to be further addressed in subsequent meetings. There should be no limitation on where it may be administered. Some hospitals in Washington, DC have parent/guardian sign waiver and family administers oil.
15. What are appropriate dosages for the cannabidiol oil and THC-A oil in treating epilepsy, i.e., what constitutes a 30 day supply?	The panel agreed this is a difficult question to answer as it can vary much from patient to patient, however, an approximation is between 20 – 30 mg/day of cannabidiol oil and between 1-100 mg/day of THC-A oil. Ms. Juran indicated she was informed by the Connecticut Department of Consumer Protection that a dispenser in CT may dispense no more than 2.5oz of oil and that a record of equivalency for how much flower was used to create the 2.5oz of oil must be maintained by the facility and recorded on the product's label.
Action Item:	**Ms. Juran will research how other states define a 30-day supply and counsel will research how the board may interpret the legal requirement for essentially defining a 30-day supply.**
16. Should there be any minimal age restrictions for who may be administered the oils?	The agreement of the panel is there should be no age restriction.
17. How should one test for quality and potency, e.g., methods, in-house testing, outside laboratory, acceptable	The panel discussed the differences between independent lab testing and in-house testing methods for quality and potency. It was thought that independent lab testing may be preferred and more economical. However, it may be difficult to find independent labs in Virginia to test the product. Testing would need to occur in Virginia. Existing labs with

levels, etc.?	DEA registration may need to build new facility not associated with DEA registration. Testing should include cannabinoid profiling, analysis of pesticides and residual solvents, terpene testing/analysis, and microbial screening. Florida is moving toward independent third-party testing. Dr. Toor indicated bioavailability should also be determined. Neurologists often run tests to determine blood level of cannabinoids.
18. If outside labs are used, do they maintain a particular accreditation? Are there labs in Virginia that could perform the appropriate testing?	Discussed with item #17.
19. Are there population groups that should not be eligible for the oils, e.g., inmates within the Department of Corrections?	The panel agreed that the oils should be available to all populations.
20. What is the maximum number of patients that a practitioner should be allowed to issue a written certification?	The panel discussed the concern that limiting the number may exclude patients in areas where only one or two physicians may be permitted to prescribe the oils in certain geographical areas. Many felt there should not be a maximum number. The panel discussed a maximum number of 600 active patients per physician with ability to petition for a greater number, if necessary.
Action Item:	**Ms. Juran will research if other states address the number of patients that a practitioner may issue a written certification and counsel will research how broadly this requirement in law may be interpreted.**
21. Is it reasonable that all persons working in a pharmaceutical processor should be registered with the Board? Should they all be required to be a pharmacist or pharmacy technician?	The discussion on the panel was mixed responses and it was agreed that the board does not currently have the authority to license individuals other than pharmacists and pharmacy technicians.
22. Is it appropriate to require either the physician or the patient to submit a copy of the written certification to the board, issue the patient a registration card with or without a photo,	Ms. Whitsett stated that she agreed with a photo ID for the patient. Dr. Toor and Dr. Whiting both agreed that this is an undue burden for the patient. There was discussion that the patients should be able to register at the prescribers' office if the patient is unable to register on their own.

and require the patient, parent or guardian to carry the registration and original written certification when in possession of the oil?

Action Item:

Ms. Juran to report back on how DHP could possibly structure the registration process.

There were comments that there is a general need for education regarding the positive use of cannabinoids medically. Additionally, a panel member questioned whether pharmaceutical processors could legally continue to produce oil if FDA were to approve a commercially produced oil.

ADJOURN:

Next meeting will take place on July 26, 2016 at 10:00am.

With all business concluded, the meeting adjourned at approximately 3:00 pm.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

7/26/16
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